K080890

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name
Proprietary Device Name: SmartSPOT PrimaX

Establishment Name and Registration Number of Submitter

APR 29 2008

Name: CMT Medical Technologies Ltd. (CMT hereafter)
Registration: 8030112
Submission contact: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

Device Classification

Product Code:	LLZ
Regulation Number:	892.2050
Common Name:	PACS - Picture archiving &communications system
Classification Name:	Picture archiving and communications system
Regulatory class:	Class II

Reason for 510(k) Submission
Special 510(k) Submission

Identification of Legally Marketed Equivalent Devices
K961307 SMARTSPOT

Device Description
The SmartSPOT PrimaX is a high-resolution digital imaging system designed for Digital Spot Imaging. The system is based on a PC Workstation running Windows XT as the operating system. The legally marketed SMARTSPOT K961307 has been modified: To improve its cost effectiveness, aging technologies and components (hardware and software) have been redesigned. The device major functions and principle of operation were not changed.

Indications for use
The SmartSPOT PrimaX enhances the quality of the fluoroscopy image, enables acquisition and display of high quality resolution (1024X1024 pixels) radiographic images and gives the user the possibility to perform advanced studies involving image digital subtraction, such as Roadmapping and DSA that were not possible with conventional technique.

Fields of application of the system are: gastrointestinal examinations, interventional procedures, peripheral angiography studies, urology examinations and other routine fluoroscopy studies.

Safety & Effectiveness
The device has been designed verified and validated complying with 21CFR 820.30 regulations. Tests data demonstrate that the SMARTSPOT PrimaX meets the required specifications. No adverse affects have been detected.

Substantial Equivalency
It is CMT opinion that the SmartSPOT PrimaX is substantially equivalent in terms of safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 2008

CMT Medical Technologies Ltd.
c/o Mr. Dan Laor
Quasar Quality Ltd.
6 Sireni
HAIFA 32972, ISRAEL

Re: K080890
Trade/Device Name: SmartSPOT PrimaX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: LLZ
Dated: March 27, 2008
Received: March 31, 2008

Dear Mr. Laor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080890

Device Name: SmartSPOT PrimaX

Indications For Use: The SmartSPOT PrimaX enhances the quality of the fluoroscopy image, enables acquisition and display of high quality resolution (1024X1024 pixels) radiographic images and gives the user the possibility to perform advanced studies involving image digital subtraction, such as Road mapping and DSA, that were not possible with conventional technique.
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Prescription Use: YES AND/OR Over-the-Counter Use: NO
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080890